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Patent Application Docket No. UTR-104

Examining Group 1617

Q9/654,357

Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATE

DEMARK OFFICE

DECLARATION UNDER 37 C.F.R. § 1.131

Examiner

Helen Nguyen

Art Unit

D.C. 20231 on Aug.

1615

**Applicants** 

Michael B. Zemel, Hang Shi, Paula C. Zemel

Serial No.

09/654,357

Filed

September 1, 2000

For

Materials and Methods for the Treatment or Prevention of Obesity

Commissioner of Patents and Trademarks Washington, D.C. 20231

## DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

DR. MICHAEL B. ZEMEL, DR. HANG SHI, AND DR. PAULA C. ZEMEL DECLARE:

- THAT we are co-inventors of the invention disclosed and claimed in U.S. 1. Application Serial No. 09/654,357.
- 2. THAT said invention was completed in the United States prior to January 2000, as shown by the following exhibits. We conceived and reduced to practice methods for the stimulation of lipolysis in animals by increasing the amounts of dietary calcium consumed by these animals. Dietary calcium is provided in the form of calcium carbonate or powdered non-fat milk. Exhibit 1 shows that increasing dietary calcium stimulates lipolysis. The effects of a high calcium diet on adipocyte lipolysis was assayed using a glycerol release assay as described in Example 2 of the above-identified patent application.

3. That Exhibit 1 is a copy of pages taken from a laboratory record created and maintained in the normal course of laboratory operations, prior to January 2000. The completion date of the experiments and analyses recorded in these laboratory notebook pages have been redacted. We hereby attest that these redacted dates are prior to the critical date.

Swear

We hereby further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By: Michael B. Jemel, Ph.D.	Date: <u>August 21, 2001</u>
By: Hang Shi, Ph.D.	Date: Aug 21. 200
By:Paula C. Zemel, Ph.D.	
Missing	paula 's signature.  Dassone that all
S:\HOME\Jonesj\FCE\UTR\104\131 declaration.doc/DNB/jaj	need to sign.  OK paula 's sign is on the following pages.



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STD !	1 540 0				
STD 1	139 0	.000			
MEAN Silver		SD=	ა. იიი	RSD=	0.483
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	2.44 3.060 2.		0.009	RSD=	0.072
3TD 3 3	3.097/2	. 200 Enn			
MEAN=	3.078		0.026	DOD-	0.044
STD 4 8	1.319 5	രവവ	3.025	KDD-	0.844
STD 4 8	.315 5.	000			
MEAN= 8	. 317	SD=	0.002	RSD=	0 024
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TTD 1 2					
900 1 1 90Ah= 2		000		_	
	.000 .988-0.	SD=	0.007	RSD=	0.350
	.001 0.				
1. AN 1 2			0.009	per	n par
.46 3 8		100	0.000	130-	الراد ، ن
		100			
	. 405	SD-	0.016	RUD =	<b>0.19</b> 0
S70 i !		250			
STD 4 1		250			
MLAN = -1	0.76 5 3 0	SD =	J.014	RSD-	0.130
31D 5 1 5TD 5 1		500			
MEAN = -1			0.::30	DOD	<b>a</b>
		000	000	KSD-	0.000
	5. 15 1.	000			
MCAN !	5,44	SD-	0.009	RSD≃	0.068
	.773 0.	074			
1 4	.702 0.				
10, M 11 11			0.000	RSDH	0.000
$\begin{pmatrix} 2 & 1 \\ 2 & 1 \end{pmatrix}$	.096 a.	⊕35 эs			
IL MEAN = 0	.970 u. .085	000 30±	0.000	pgn	000
	.028 O.		0.000	K50-	0.000
	.022 0.				
			0.000	RSD=	0.000
24 MEAN= 0 4 3	. 148-0.	0161.			
	.173-0.				
	.015	SD=	0.001	RSD=-	6.667
5 3	. 473 0. . 479 <b>0</b> .	UU2 .	•		•
MEAN= 0			0.000	DGD-	n nnn'
6 5	.002. (c.	092//	0,000	たらひ=	.,
	.085 0.		ζ.		
	.091	SD=	ò.ooo ·	RSD=	0.000
State Service State 97	C 40 0 .				

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8 5.955 0.139
           5,933 0,138
        8
                                  RSD= 0.000
   MEAN=
           0.138
                     SD=
                          0.000
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           2.705-0.040L
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                                  RSD = 0.000
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                                  RSD = 0.000
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           0.078
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           4.835 0.073
       26
       26
           1.816 0.076
135 MEAN =
                          0.001 RSD= 1.298
           0.077
                     3D=
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           5,822 0,132
       27
 4aMEAN=
                          0.006 RSD= 4.724
           0.127
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          52.061-0.076L
      28
         12.028-0.077L
                          0.000 :RSD= 0.000
     EAN= 0.052 1 SD
                       = 0.001 ARSD=
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0.052
                       SD=
         30
              5.045 0.089
         30
              5.008 0.087
  155 MEAN=
             0.088
                        SD=
                             0.001
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             5.409 0.109
         32
             5.397 0.109
             0.109
                       sn =
                             0.000
                                     RSD= 0.000
         33
             3.110-0.0181
         33
             3.110-0.01SL
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                             0.000
                                     RSD= 0.000
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             3.300-0.002L
        34
             3.410-0.001L
  | 5 MEAN= -0.002
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                                     RSD= 0.000
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             3.404-0.001L
        35
             3.113-0.0171.
  TAMEAN= -0.009
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                                    RSD=-122.2
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             2.348-0.060L
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                                    RSD= 0.000
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           -0.020
                      SD=
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                                    RSD= 0.000
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            2.640-0.044L
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                                    RSD= 0.000
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            2.802-0.035L
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            2.746-0.0381.
    MEAN =
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                      SD-
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                                    RSD=-5.406
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            5.112 0.093
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                      SD=
                                    RSD= 14.28
                            0.012
       42
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       42
            5.577 0.118
    MEAN=
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                      SD=
                            0.001
                                   RSD= 0.840
       43
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            3.652 0.012
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                                   RSD - 0.000
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            5.971 0.091
       44
            5.000 0.090
 0.090
                                   RSD= 0.000
                            0.000
       45
            3,980 0.030
       45
            3.985 N.031
  5 MEAN=
            0.030
                      SD =
                           0.000
                                   RSD≈ 0.000
       46
            4.219 0.044
       46
            4.212 0.043
≲α MEAN=
           0.043
                     SD=
                           0.000
                                   RSD = 0.000
       47
           4.821 0.077
       47
           4.703 0.075
& S MEAN=
           0.076
                     SD=
                           0.001
                                   RSD= 1.315
       48
           4.956 0.084
       48
           4.955 0.084
9 almean=
           0.084
                           0.000
                     SD=
                                   RSD= 0.000
       49
           4.111
                  0.038
      49
           4.082 0.
                    7036
   MEAN=
           0.037
                     SD=
                           0.001
                                   RSD = 2.702
       50
           4.999 0.087
       50
           5.004 0.087
O &MEAN=
                           0.000
           0.087
                     SD=
                                   RSD = 0.000
      51
           4.033 0.033
      51
           4.046 0.034
106 MEAN=
           0.033
                     SD-
                           0.000
                                   RSD= 0.000
      52
           4.807 0.076
      52
           4.792 0.075
1 a_MEAN=
           0.075
                     SD=
                          0.000
                                  RSD = 0.000
      ъз
           5.049 0.089
      53
           5.044 0.089
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0.037
                           0.001
                     SD=
           4.999 0.087
       50 5.004 0.087
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           0.087
                     SD=
                           0.000
                                   RSD = 0.000
      -51
           4.033 0.033
       51
           4.046 0.034
106 MEAN=
           0.033
                     SD∸
                           0.000
                                   RSD= 0.000
       52
           4.807 0.076
       52
           4.792 0.075
11 a MEAN=
           0.075
                     SD=
                           0.000
                                  RSD = 0.000
       53
           5.049 0.089
       53
           5.044 0.089
115 MEAN=
           0.089
                     SD=
                          0.000
                                  RSD = 0.000
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           5.674 0.124
   MEAN=
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                     SD=
                          0.000
                                  RSD = 0.000
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           5.793 0.130
2-5MEAN=
           0.131
                     SD=
                          0.001
                                  RSD= 0.763
      56
           5.551 0.117
      56
           5.523 0.115
Samean.
           U.116
                    SD=
                          0.001
                                  RSD= 0.862
      57
           3.558 0.007
      57
           3.551 0.007
135MEAN=
                    SD=
          0.007
                          0.000
                                  RSD= 0.000
      58
          6.217 0.154
      53
          6.194 0.153
14amean=
          0.153
                    SD=
                          0.000
                                  RSD= 0.000
      59
          i.984-0.080L
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          1.982-0.080L
15 MEAN= -0.080
                    SD=
                          0.000
                                  RSD= 0.000
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          5.393 0.108
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          5.395 0.108
  aMEAN=
          0.108
                    SD=
                          0.000
                                 RSD= 0.000
      61
          5.425 0.140
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          5.424 0.110
  MEANE
          0.110
                    SD=
                          0.000
                                 RSD= 0.000
      62
          2.896-0.029L
      62
          2.897-0.029L
blumEAN= -0.029
                    SD=
                         0.000
                                 RSD = 0.000
   O, 63
          5.112 0.093
          5.154 0.095
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          0.094
                    SD=
                         0.001
                                 RSD= 1.063
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          5.849 0.133
  MEAN =
          0.133
                    SD=
                         0.000
                                 RSD = 0.000
          5.858 0.134
     `65
     65
          5.859 0.134
  MEAN =
         0.134
                   SD≕
                         0.000
                                 RSD= 0.000
     66
          5,021 0.088
     66
         5.011 0.087
  MEAN=
         0.087
                   SD=
                         0.000
                                 RSD= 0.000
         5.401 0.109
     67
     67
         5.413 0.109
  MEAN=
         0.109
                   SD=
                         0.000
                                 RSD= 0.000
     68
         5.938 0.138
     68
         5.860 0.134
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         0.136
                   SD=
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         5.256 0.101
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                                RSD= 6.603
   70 2.213-0.067L
          2.209-0.067L
                 .;: SD=
                        0.000
                                RSD= 0.000
                                RSD = 0.781
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• "					
	8	0.221	0.1988	1.11167 0.947136	
ACTH( con	100nM	1)			
1a		0.038	0.3977	0.095549	
1b		0.057	0.3636	0.156766	
2a		0.058	0.4902	0.118319	
2b		-,	0.4441		
3b		0.056	0.3771	0.148502	
4a		0.035	0.5005	0.06993	
4b		0.006	0.5643		0.010633
avg				0.117813	
high-Ca	а				
5a		0.017	0.4475		0.037989
5b		0.177	0.3302	0.536039	
6a		0.21	0.4576	0.458916	
6b		0.075	0.4078	0.183914	
7a		0.174	0.3832	0.454071	
7b		0.098	0.5349	0.183212	
8a		0.115	0.4088	0.281311	
8b		0.154	0.2215	0.69526	
avg				0.39896	
medium	n-dairy				
9a		0.166	0.5304	0.312971	
9b		0.107	0.4747		
10a		0.169	0.53	0.318868	
0b		0.103	0.5327	0.193355	
11a		0.155	0.3235	0.479134	
11b		0.172	0.3931	0.437548	
12a		0.216		0.944056	
12b		0.226	0.2761		
avg				0.466235	
high-da	iiry	0.007	0.0045	0.504745	
13a		0.207		0.524715	
13b		0.069		0.172543	
14a		0.253		0.824104	
14b		0.237		0.832455	
15a 15b		0.196		0.964092 0.566524	
16a		0.198 0.023	0.3495 0.4219	0.500524	0.054515
16b		0.023		0.433526	0.004010
avg		0.10	0.4152	0.436325	
419				3.010001	

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